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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,691	02/25/2002	Stephen Donovan	D-3018	5311

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EXAMINER	
MARX, IRENE	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 01/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/082,691	DONOVAN, STEPHEN	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *10,11,13-16,20,21,28 and 29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9, 12, 17-19, 22 -27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO 152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Applicant's election with traverse of Group III, claims 1-9, 12, 17-19, 22-27 is acknowledged. The traversal is on the ground(s) that because all of the groups of claims identified by the Examiner relate the treatment neurogenic inflammation pain, and thus, are directed to a single invention.

However this is not found persuasive because the methods are of a different scope and the references which would be applied to one method would not necessarily anticipate or render obvious the other method.

Moreover, as to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues also exists.

Clearly different searches and issues are involved with each group.

For these reasons, the restriction requirement is deemed proper and is adhered to. The restriction requirement is hereby made FINAL.

Claims 10-11,13-16, 20-21 and 28-29 are withdrawn from consideration as directed to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 12, 17-19, 22 -27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague, indefinite and confusing in the recitation of "treating pain" without an indication of the length of the effect. Is it a nanosecond, a second, 10 minutes, an hour, 3 hours, a day, etc. The claim is also vague, indefinite and confusing in the recitation of an "effective amount" of a composition comprising a botulinum toxin component and a substance P component. The relative amounts intended for each of the components and their relationship in

the composition is not set forth with sufficient particularity. Moreover, it is apparent that by administering a sufficient amount of botulinum toxin alone pain may be eliminated by killing the patient.

Claim 7 is vague and indefinite in the recitation of "**a** substance P". It is not apparent that a variety of compounds designated "substance P" are available. Thus, the proper terminology would be to omit "a" in this context.

Claim 8 is vague and indefinite in the recitation of a "precursor of substance P", since essentially any compound can be deemed to be an "ultimate precursor", including any food product.

Claim 9 is vague and indefinite in the recitation of "substance P analogue, since the extent of the similarity is not indicated. It is a structural analogue or a functional analogue, for example. How is analogy determined?

Claims 22 through 27 are vague, indefinite and confusing in the recitation of "in an amount that will reduce pain in a patient by...". Is this the "effective amount"? The amount required to reduce pain cannot be readily determined, since "pain" is dependent on the pain threshold and perception of the individual to be treated and is relative with respect to the severity of the condition and of the pain. Pain is a psychological experience with an emotional dimension It is uncertain how reduction of pain is to be assessed or measured for quantization.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9, 12, 17-19, 22 -27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4-7, 9, 11-20 of U.S. Patent No. 6,500,436. Although the conflicting claims are not identical, they are not patentably distinct from each other because the conflicting claims are similarly directed to methods a treating pain, including neurogenic inflammation pain due to arthritis with the same composition comprising a botulinum toxin component and a substance P component to a patient.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by First.

The claims are directed to a method for treating neurogenic inflammation pain by administering a composition comprising a botulinum toxin component and a substance P component, including analogues and precursors thereof, to a patient.

First teaches the treatment of pain due to neurogenic inflammation such as in arthritis with botulinum toxin and/or subunits thereof. The administration of this compounds results in the presence of substance P or a functional analogue or precursor thereof as a neuropeptide mediator of neurogenic inflammation (col. 3, lines 1-5). Thus, upon administration a composition comprising botulinum toxin and substance P or a functional analogue or precursor thereof can reasonably be presumed to be present at the required location. The effect of reduction of pain is an inherent effect of the composition.

Claims 1-9, 12, 17-19 and 22-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over First.

The claims are directed to a method for treating neurogenic inflammation pain by administering a composition comprising a botulinum toxin component and a substance P component, including analogues and precursors thereof, to a patient.

First teaches the treatment of neurogenic inflammation such as in arthritis with botulinum toxin and/or subunits thereof, wherein the reduction of pain is a natural effect thereof.

The reference may differ from the invention as claimed in that the composition is not explicitly disclosed as being administered with substance P, analogues or precursors thereof. However, given that substance P is one of the neuropeptides implicated as mediators of neurogenic inflammation (col. 3, lines 1-5), upon administration a composition comprising botulinum toxin and substance P, analogues or precursors thereof would reasonably be expected to be present at the required locus and have the required effect of reducing pain due to inflammation.

It is noted that the data of record in the as-filed specification wherein pain due to neurogenic inflammation pertains exclusively to botulinum toxin and substance P conjugates. There is nothing on the record to suggest that the administration of the addition of substance P, analogues or any precursor of substance P in any amounts whatsoever in conjunction with botulinum toxin has a different effect with respect to the treatment of pain due to neurogenic inflammation than the administration of botulinum toxin by itself.

Accordingly, one of ordinary skill in the art would have had a reasonable expectation of success in treating pain due to neurogenic inflammation using botulinum toxin alone or in conjunction with substance P, analogues or precursors thereof, compounds recognized to be present at the site of effect of botulinum toxin.

It would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of First for the treatment of pain due to neurogenic inflammation by administering botulinum toxin together with substance P, analogues or precursors thereof given that these compounds are normally present at the site of effect of the toxin for the expected benefit of successfully reducing the pain due to neurogenic inflammation in the treatment of arthritis a very desirable effect for the many patients affected by arthritic pain.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is 571-272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-9000.

Irene Marx
Primary Examiner
Art Unit 1651